

NEW

INSTRUCTIONS FOR PREPARATION OF MERIT REVIEW APPLICATIONS

Effective September 2002

These guidelines were developed to help you prepare a VA Merit Review Application. For additional information you should review the VA Merit Review Award Program Handbook (VHA Handbook 1202.1) which can be access from the Iowa City Research website (www.research.iowa-city.med.va.gov). All components listed starting with VA Form 10-1313-1 (page 1 of the application) need to be addressed. Contact Steve Breese, Administrative Officer for R&D at extension 7669 or steve-breese@icva.gov concerning eligibility for submission of VA applications and Nancy Spevacek at extension 7645 or spev@icva.gov for the appropriate VA forms (10-1313's, Animal Care and Use Forms and Biohazard Forms). Please call us with any questions you may have concerning the VA Merit Review program.

GENERAL INSTRUCTIONS

The local deadline for the March and September submissions are as follows:

- Waiver to perform research off-site – January 10 – August 10
- Letter of Intent for Funding exceeding \$150,000 per year – January 10 – August 10
- Draft for local review – January 15 - July 15
- Animal Care and Use forms are due in the Research Office – January 15 – July 15.
- Final proposal including all approvals must be in the Research Office-February 13 - August 15.

Off-Site Research. Any investigator whose lab is located at the University must discuss research space with Steve Breese (x7669 or steve-breese@icva.gov). Investigators submitting merit reviews must have assigned research space at the VAMC or UI leased space. In the resources section of the narrative reference must be made the where the VA lab is located, including room numbers, and square footage.

Request for funding exceeding \$150,000 per year. Applicants requesting annual budgets exceeding \$150,000 exclusive of equipment and Principal Investigator (Ph.D.) salary costs must submit a Letter of Intent (LOI) prior to proposal submission. Submit the LOI's to the Research Office no later than January 10 or August 10. Guidelines are available from the Research Office (7645).

Contact Nancy Spevacek (spev@icva.gov, ext 7645) or Steve Breese (steve-breese@icva.gov, extension 7669) for any questions or concerns regarding the merit review guidelines.

2. SPECIFIC INSTRUCTIONS FOR PROPOSAL PREPARATION: Obtain a Merit Review Program packet from the ACOS/R&D. The packet should contain all the forms necessary for completing the application and any additional forms required for local review. Official VA research forms in PDF and Word format can be found at <http://www.va.gov/resdev/fr/forms.cfm> or the Iowa City Research web site <http://www.research.iowa-city.med.va.gov>. Use a clear, black font when filling out all forms. Font size for all text shall be at least 11 point. Certain forms must be submitted electronically through the PROMISE system. Staff of the ACOS/R&D will assist in printing and submitting these forms.

a. **Page 1; form 10-1313-1. Merit Review Application**

(1) Blocks 1, 2, and 3. Left blank.

(2) Block 4 (review date). The season and the year for the upcoming round of review. For example if the submission deadline is March 15, 2004, the review date is spring 2004. If the submission deadline is September 15, 2004, the review date is fall, 2004.

(3) Block 5 (facility number). Type in 584

(4) Block 6. Type in VA Medical Center, Iowa City, Iowa

(5) Block 7. The social security number of the PI. *Note: the social security number should appear on the original form only. It shall be redacted from all copies of the proposal.*

(6) Block 8. The last date the PI submitted a MERIT application regardless of its outcome. A blank indicates that no MERIT proposal on any topic, including EPIM and CLIM, has ever been submitted.

(7) Block 9. The Last Name, First Name, Middle Initial, and degree(s) of the PI. Also, include the PI's VA telephone number with extension (if needed), mailing address, and e-mail address.

(8) Block 10. The title of the project, which may not exceed a total of 72 characters, including spaces. The title should describe the research activity.

(9) Block 11. The total budget for each year of requested funding and the total amount for all years of the program. The amounts and duration shall agree exactly with the totals on 10-1313-3 and 10-1313-4. All budget totals and subtotals shall be rounded to the nearest \$100 (see instructions for forms 10-1313-3 and 10-1313-4).

(10) Block 12. The employment status in VA paid 8ths of the PI at the time of application or have their eligibility approved by VA Central Office prior to submission of MR application.

(11) Block 13. The PI's source of employment at the time of application. The majority of M.D. investigators are patient care salaried, and Ph.D. investigators are research cc 103.

(12) Block 14. If the PI, at the time of application, has not had MERIT funding in the past 5 years, the “NEW” box should be checked; otherwise check the “ONGOING” box. The “No. Projects in Program” may be left blank.

(13) Block 15. Under “Program” enter “821” Medical Research Service and under “Cost Center” enter CC103, which is the cost center designation for Merit Review awards.

(14) Block 16. Primary Research Program Area and Primary Specialty Area are selected from a list in a list on the RDIS Investigator Data form (call the Research Office for a copy extension 7645).

(15) Block 17. Insert the service the investigator is associated with at the VA medical Center, e.g., Infectious Diseases, Medical Service.

(16) Block 18. Enter PI’s current Academic Rank, primary academic department, and the name of the university affiliation.

(17) Block 19. Program Use; check each block that applies:

(a) *Human subjects*. This box must be checked if the research has any relation to human beings, even if the initial review board (IRB) has found the research to be exempt.

1. Check this box if human subjects are exposed to manipulations or interventions, interact with researchers, or can be identified from data collected, even if the data already exists.

2. Also, check this box if human tissues are obtained. Tissues include, but are not limited to, biopsies, blood, cerebrospinal fluid, urine, feces, saliva, nail clippings, hair, sweat, and tears.

3. Check the box if human tissue is obtained from surgery or autopsy, tissue banks, other non-profit sources, or commercial sources.

4. Work on human immortalized cell lines is not considered research on human subjects, but does involve biohazards.

5. If the research involves banking of human specimens, gene testing, gene transfer, and/or stem cells, it must comply with all VA policies and guidelines regulating the conduct of such activities.

(b) *Animal subjects*. Check this box if animals or any tissue derived from animals are used in the proposed project, even if obtained from a tissue bank or commercial sources.

(c) *Investigational Drugs or Devices*. Check the appropriate box if the use of investigational drugs or devices with human subjects is proposed.

(d) *Radioisotopes*. If radioisotopes are used, check the “Radioisotopes” box and include appropriate information in the biohazard form. The local Radiation Safety Committee must approve the use of radioisotopes before any studies contained in the application may be run.

(e) *Biohazard*. Almost all research submitted to MRS involves biohazards. Blood, however obtained, cerebrospinal fluid, and all body secretions and excretions, e.g., urine, feces, saliva, sweat, and tears, are biohazards. Most chemicals used in laboratories are biohazards.

1. A checklist of biohazards by category is provided on the first page of Appendix G of VHA Handbook 1200.8. If the research uses any of the products listed in the appendix, the Biohazards box must be checked.

2. Questions about research safety documentation should be directed to the Iowa City Research Biosafety Officer.

(18) **Block 20**. Summarize the PI’s research support for the last 3 fiscal years in chronological order. “Non-VA” includes all other sources of research funding other than VA.

(19) **Block 21**. Insert the date the PI entered or will enter VA duty (all applicants must be VA employees by the time the application is funded).

(20) Signatures and dates in this block shall be within 6 months of the submission due date, and the date the ACOS/R&D signed shall be subsequent to the approval date of the R&D Committee. The signature of the ACOS/R&D signifies the completeness and accuracy of the contents of the application. The signature of the PI signifies responsibility for the proposal contents, the scientific responsibility for the proposed projects, and agreement to follow VA policies for acknowledging VA support and intellectual property rights. “Per” “by” or, “for” signatures are not acceptable.

b. **Page 2, Summary Description of Project/Program; form 10-1313-2**. Because MRS no longer funds multiple projects as part of a Merit Review program, check the “Project” box throughout this application.

(1) The PI’s name and project title must be exactly as written on Page 1 (10-1313-1).

(2) Use keywords that describe the disease, system, mechanism being studied, and major methods/techniques used. Because the keywords are used for searches and portfolio related issues, only Medical Subject Headings (MeSH) terms may be used. The ACOS/R&D has a MeSH terms book, which is also available at the medical center library or may be obtained online (<http://www.nlm.nih.gov/mesh/meshhome.html>).

(3) **Summary description**: The summary description (abstract) of the proposal provides information about the hypotheses to be tested, specific objectives, relevance, subject population, procedures to be used and significance of potential new findings. It must include enough information so that the proposal can be referred to the appropriate Merit Review Subcommittee and reviewers. Use only the allotted space.

c. **Page 3, Table of Contents.** Use Table 2 as the format for the Table of Contents. Indicate N/A for not included or non-applicable items. Consecutively number all pages in the application and place the starting page number for each section in the Table of Contents.

TABLE 2 – Table of Contents

10-1313-1 - front page	1
10-1313-2 - (abstract)	2
Table of Contents	3
10-1313-3 - first year budget	4
10-1313-4 - all years budget and justification	5
Investigators’ Biographic Information	
Starting with PI (Forms 10-1313-56, 8;	
Description of any overlap	
Follow with complete sets from each co-investigator.	—
Text of Proposal	
Response (resubmitted applications only, not to exceed 3 pages)	—
List of acronyms/abbreviations	—
Narrative: Parts 1-4 (not to exceed 25 pages)	
1. Rationale	—
2. Background and Significance	—
3. Work Accomplished	—
4. Work Proposed	—
Human Studies Section	—
Animal Studies Section	—
Resources (1 page)	—
Publications from last funding period	—
Literature citations (not to exceed 4 pages)	—
Administrative Issues	
R&D Committee approval memorandum	—
VAMC director’s memorandum	—
Other Letters of Endorsement	—
VACO Approvals: Exceptions, Waivers or Permissions letters (eligibility, acceptance into program, off-site location, exceeding budget cap)	—
Previous review (resubmissions only)	—
Reviews	—
10-1313A-front page (Summary Statement)	—
10-1313A-continuation (Summary Statement Text)	—
Other Attachments	—
“Research Priority Area - Portfolio” Form	
Appendix (7 collated sets). List of items in Appendix	

d. Page 4, Current Funds and First Year Requests for Program/Project (Form 10-1313-3). At the top of the form check the “Project” box.

1) All budget subtotals shall be rounded to the nearest \$100.

(2) Recurring budget (i.e., total budget less PI salary and equipment) may not exceed \$150,000 per year nor may the equipment request exceed \$50,000 unless prior approval has been obtained (see Appendix F).

(3) MRS recommends requesting the following project durations:

(a) Investigators with less than 3 years of independent, nationally peer-reviewed funding as a PI shall limit their project duration to 2 or 3 years.

(b) Investigators with 3 to 5 years previous independent funding may request 2 to 4 years of funding.

(c) Investigators with more than 5 years previous independent funding may request 2 to 5 years of funding.

(d) If it is believed that the work cannot be accomplished within this suggested timeframe, the transmittal memorandum from the Chair of the R&D committee shall provide a detailed justification for the additional years requested. Under no circumstances can more than 5 years of funding be requested.

(4) Personnel. Starting with the PI, list all personnel involved in the project. In the appropriate columns list their names (with Grade and Step in parentheses), role in the research proposed, the percent effort each will devote to the project, and whether or not salaries are requested. Salaries shall include fringe benefits (35%) for all personnel to be paid from MRS funds.

(a) The salary requests should be proportional to the percent effort listed (non-clinician PI's salaries are an exception, see below). Secretarial salaries are not allowed. Physicians and dentists, and, in most cases, nurses may not receive salaries from the medical research and prosthetics appropriation. PIs shall not be paid through Inter-agency Personnel Act (IPA) agreements.

(b) If the PI is a non-clinician, salaried by research appropriation CC103, in the “% effort” column the PI shall indicate the actual percent effort that the investigator will expend for the research described in this application only. However, in the “First Year Requested Funds” column, the non-clinician PI may request salary consistent with the person's total VA effort.

1. Total VA effort includes the work anticipated in this application, participation in other VA and non-VA research, service toward core facilities, teaching, supervision of students, participation in research centers, service on committees, etc. For example, a non-clinician PI listing 40% effort for the proposed research, 20% effort as an uncompensated co-investigator on an NIH grant, 15% service to research administration, and 10% teaching and mentoring would request 85% of the investigator's full-time equivalent salary.

2. Salary support may be requested only for activities that are uncompensated from other sources such as the academic affiliate or other funding agencies. Any differences in the percent effort for the work proposed and total VA effort (salary support) shall be described fully in the budget justification.

(c) If the PI is a Research Career Scientist (CC110), list the percent effort the person will devote to the proposed research, but no salary may be requested. In the budget justification discuss the investigator's contribution to the proposed research only.

(d) All co-investigators, collaborators, and technical staff, whether paid or not, should be listed in the personnel section. There are restrictions on who can be paid directly by the VA. Check with the local Research Service to ensure that salary is not requested for a person who cannot be paid directly by the VA.

(e) If a person is paid through a contract for services or an IPA, put "IPA" in the column for requested funds. List the specific costs of IPAs in the "all other expenses" section of the budget.

(f) If warranted, non-clinician Ph.Ds. may be hired as postdoctoral scientists to do the technical aspects of the research.

(g) *Other personnel.* Check the list of unauthorized budget items (Table 3) for personnel who may not be included in proposal budgets.

(5) Include in the "Current Year Funds" column all funds allocated by MRS to the investigator for the 12 months preceding the first year request.

(6) Consultants. A consultant may not receive a fee of more than \$2,500 per year and the consultant's involvement must be fully explained in the budget justification. There are limitations on payment to consultants – contact the office of the ACOS/R&D

(7) Equipment. Although the form 10-1313-3 states that all equipment in excess of \$3,000 must be listed, MRS requires that each item of equipment, no matter the cost, shall be listed separately and thoroughly justified on form 10-1313-4. Equipment consists of relatively permanent, fixed assets that are essential to the completion of the proposed research.

(a) When feasible, equipment shall be purchased in the first year of the project. If properly justified, MRS will consider equipment requests in later years of the project. The terminology such as 'misc. small pieces of equipment' shall not be used.

(b) Expendable items should be requested as supplies.

(c) Approval must be received in advance to request equipment totalling more than \$50,000 (see Appendix F for deadlines and instructions).

(8) Supplies. Itemize expendable supplies in separate categories, such as glassware, chemicals, radioisotopes, etc. Categories totaling less than \$1,000 do not need to be itemized. If animals are to be purchased, state the species, cost per animal, and number to be purchased in the first year.

(9) All Other Expenses. List all other expenses by major category, including costs for publications, rental and contractual fees. Include the daily (*per diem*) and total charges for Animal Research Facility maintenance of all animal subjects required in the research. Check Table 3 for a list of unauthorized items. List service contracts for equipment utilized only for the proposed research. If the equipment is used by multiple research projects, request a proportionate amount of the service contract. Travel costs are permitted for project staff if the travel is directly related to the proposed research, but travel costs for scientific meetings as well as registration fees and expenses for books and journals are not permitted.

TABLE 3. Unauthorized Budget Items*

PERSONNEL

Increases over years to account for inflation or salary increases
Dishwashing aide
Summer students
Graduate Students

EQUIPMENT

Office Furniture

SUPPLIES

Office supplies

OTHER (Usually supplied by local facility)

Books and journals
“charge-back costs”
Registration and travel to scientific meetings
Medical media/ slide preparation/photography
Photocopying charges
Maintenance costs which are unjustified
Maintenance costs for core or shared equipment
Library computer searches
Word processing
Long distance phone charges
Cylinder demurrage charges
Communication costs
Radioisotope waste disposal
Biohazard waste disposal

e. Estimated Expenses For Program/Project (Form 10-1313-4). At the top of the form, check the “Project” box.

(1) Enter the totals for each budget category for all additional years of support requested. The total operating expenses for the first year shall be identical to the total indicated on VA forms 10-1313-1 and 10-1313-3. Do not include inflationary increases in any of the budget categories or cost-of-living increases, within grade increases, or anticipated promotions in the personnel category.

(2) All differences in the operating expenses between years should be fully justified.

(3) Justification. All items in the budget must be clearly justified. Use continuation pages if necessary.

(a) *Personnel*. Fully explain the role and percent effort of the PI and all personnel listed in the Personnel section of form 10-1313-3. If the PI is a non-clinician scientist, paid by the research appropriation CC103, fully describe the basis for any difference in the % effort for the work proposed and total VA effort (salary support). The signature of the ACOS/R&D on form 10-1313-1 signifies agreement to have the non-clinician PI perform the work described to justify salary.

(b) *Consultants*. Clearly explain the expertise of each consultant with regard to the proposed research. State the frequency of consultations.

(c) *Equipment*. For each item, justification should include a discussion of why the equipment is needed and why similar existing equipment (if any), whether in the laboratory, common resource equipment, borrowed, or on loan, cannot be used. Describe the equipment used in the generation of the data in the “Work Accomplished” section and its availability for the proposed research.

(d) *Supplies*. Explain how the costs for each category of supplies were derived; for example, is it based on the PI’s expense history in performing similar research?

(e) *All Other Expenses*. Items in this category should be explained in the same manner as those in the supplies category. Personnel contracts or IPAs should be fully explained including the basis for the individual’s salary.

(4) The budget totals on forms 10-1313-3 and 1313-4 must match each other as well as the totals in block 11 of form 10-1313-1. The accuracy of these items should be checked before sending the proposal.

f. **Investigator Information (Forms 10-1313-5, 10-1313-6, 10-1313-8)**. The three forms (VA Form 10-1313-5, 6, and 8) shall be completed for the PI and for each scientist who will participate in the design, performance or scientific direction of the proposed research. For those investigators devoting 5 percent effort or less, include only biographical information (VA Form 1313-5 and 6). Do not include any of the above forms for consultants or technical staff. **Note:** *form 10-1313-7 is no longer required.*

(1) Investigator's Biographic Sketch (form 10-1313-56). Follow the instructions on the form. (This is a New Form)

(3) Investigator's Total Research/Development Support (form 10-1313-8). Read these instructions carefully as they are different from previous instructions for this form. Total research support is defined as all financial resources, whether Federal, non-Federal, commercial or institutional available in direct support of the individual's research. Examples are current MERIT award, research grants, cooperative agreements, contracts, institutional awards, and awards from other VA research programs such as HSR&D, EPIM, CLIM, RR&D and REAPs/Centers. Include all currently funded and pending support. Do not include the current application as pending support.

(a) *Copy form 10-1313-8 as needed*. If the investigator has no active or pending support, write "None" in the first description box. Otherwise, starting with active awards, follow the instructions on the form for "Status". In the "Grant/Project No" box write the name of the awarding agency and the project number, if assigned. In the Grant/Project Title box, write the full title and the sub-project number, if appropriate.

(b) In the box provided for description, use the following format:

1. Role: State the investigator's role in the project (PI, co-investigator, PI of sub-project, etc.)
2. Dates of Approved/Pending Project: Indicate the inclusive dates of the project as funded or proposed.
3. Annual Direct Costs: For active awards, provide the current year's direct cost budget and for pending applications provide the proposed initial budget period.
4. Percent Effort: For an active award, provide the level of effort (whether salaried or unsalaried) as approved for the current budget period. For pending projects list the level of effort proposed for the initial budget period.
5. Major Goals: Provide a brief statement of the overall objectives of the project. If it is a sub-project on a center grant or contract, provide the objectives for the sub-project only.

(c) Using this format, continue to list all active and pending funding for the investigator.

(d) *Overlap*. After listing all of an investigator's support, in a paragraph headed "Overlap," summarize any potential overlap between the research in the proposal and any active or pending research with respect to the science, budget or the investigator's total effort. Statements such as "there are no budgetary, scientific or administrative overlaps" without any discussion of the science are not acceptable.

1. Budget overlap occurs when duplicate or equivalent budget items, such as equipment or salary, requested in the application are already funded, requested in a pending application, or provided for from another source.

2. Commitment overlap occurs when any personnel listed on the project has time/effort commitments (whether salaried or unsalaried) that exceed 100 percent. No individual listed on the project budget form may have in excess of 100 percent effort.

3. Scientific overlap occurs when substantially the same research is proposed in more than one application, is submitted to two or more funding sources, or when the research objectives and the research designs are the same or grossly similar in two or more applications, regardless of funding sources.

g. **General Instructions for Response and Narrative.** Observe the page number limitations specified in Table 4. Proposals exceeding page limitations will not be reviewed.

(1) Avoid delays and misunderstandings by carefully reading and following the instructions. Use proper English and avoid jargon. For terms that are not universally known, spell out the term for the first time followed by an abbreviation enclosed in parentheses; thereafter the abbreviation may be used. Also, include these terms in the List of Abbreviations and Acronyms.

TABLE 4: Page Limitations and Content Requirements		
Section	Page Limit	Content
Response (Revised applications)	3	See instructions, page A-13
List of abbreviations and acronyms		
Research Narrative (sections 1-4)	25	Text plus all figures, charts, tables and diagrams
Human Subjects (as needed)		See instructions, page A-15
Animal Subjects (as needed)		See Instructions, page A-16
Resources	1	See instructions, page A-17
Publications from last funding period		See instructions, page A-17
Literature citations	4	Complete citations including titles and all authors
Appendix (Supplemental methodology may not be included)		No more than five publications including accepted or submitted manuscripts. Photographs that do not copy well (include copies in Narrative). Questionnaires Other materials that do not copy well (include copies in Narrative)

(2) Observe type size specifications and margin requirements throughout the application, or it will not be reviewed. Prepare the application on standard 8.5" X 11" white paper, single-sided and single-spaced. Except for margin requirements of specific forms, allow a one-inch (1")

margin at all edges and use a single column. Multiple columns may not be used. Use standard type fonts with black letters that can be clearly copied. Do not use photo reductions. All tables, diagrams, graphs and charts, must be clear and legible.

(3) The height of the letters must be at least 11 points, the type density must be no more than 15 characters per inch (CPI) and have no more than 6 lines of type within a vertical inch. For proportional spacing, any representative section of text must not exceed a density of 15 CPI. Smaller type sizes are difficult to read and give the applicant an unfair advantage by allowing more text in the proposal. Rather than relying on font selections by word processor/printer combinations, correct type size should be verified with a standard type-measuring device. At least the minimum type size shall be used throughout the application.

(4) All figures and tables shall be included in the text. As long as it is clearly legible, type size for figures, charts, tables, footnotes and figure legends, may be smaller.

(5) Proposals that are difficult to read will be administratively withdrawn.

(6) Originals of photographs that do not copy well should be included in the appendix. Copies of these photographs also should be placed in the text of the proposal and are included in the 25-page limit. Unpublished questionnaires may also be placed in the appendix. Methods and/or procedures, even if unpublished, shall be incorporated into the Narrative and shall not be placed in the appendix. The Narrative shall be comprehensible without references to any other document, including the appendix.

h. **Response (resubmitted applications only, 3-page limit)**. A revised application will not be reviewed if it fails to comply with all of the requirements for resubmission. Prior to submitting a revised application, the PI should have received the summary statement and critiques from the previous review.

(1) The resubmission shall contain substantial revision to the content of the proposal. The revised application shall start with a Response of not more than 3 pages, which summarizes the substantial additions, deletions, and changes based on the comments and suggestions in the summary statement. If suggested changes are not made, the reasons should be explicitly stated. The 3-page response does not count toward the 25-page narrative limit.

(2) The changes in the Narrative shall be clearly marked by a vertical bar in the margin, bracketing, indenting, or a change in typography, unless the changes are so extensive that it includes the majority of the text. In that case, indicate it in the Response. Do not use underline or shading. The Work Accomplished section should include any new work accomplished since the prior submission. Acceptance by MRS to review a revised application automatically terminates the prior version.

i. **List of Abbreviations/Acronyms Used**. Provide a list of the abbreviations and acronyms used in the Narrative and define the term the first time it is used in the Narrative text. The exception is for those terms that are commonly understood (e.g., known by undergraduate biology students, such as DNA, ATP, etc.).

j. **Narrative (25 page limit including all text, figures, charts, graphs and diagrams).** The Narrative is organized into four major sections: Rationale, Background and Significance, Work Accomplished, and Work Proposed. Use the Narrative to explain 1) what the P.I. proposes to do; 2) why the proposed work is important; 3) what similar work has been done; and 4) how the proposed work will be done. All tables, graphs, charts, diagrams, and photographs shall be included in the 25-page limit; items that do not photocopy well may also be included in an appendix. The 25-page limit for the Narrative will be strictly enforced. Applications that exceed this limit or fail to comply with type size or margin specifications will not be reviewed. Within the Narrative, MRS recommends the following outline and page restrictions.

(1) **Rationale (1-2 pages recommended):**

- (a) *Statement of the Problem* - Briefly state the problem to be investigated.
- (b) *Hypotheses or Key Questions* - State the hypotheses or key questions to be answered by the proposed research.
- (c) *Specific objectives* - Briefly and concisely list the long-term and more immediate objectives of the proposed research. For long-term objectives, identify expected intermediate goals.

(2) **Background and Significance (2-3 pages recommended).**

- (a) *Background.* Briefly described the current status of research relevant to the present application and how it relates to the hypotheses or key questions. Critically evaluate existing, relevant knowledge and explicitly state the gaps that the proposed research will fill. Cite only relevant and recent literature. The Background section should be sufficiently complete to demonstrate that the PI is aware of the critical issues related to the proposal. It should not be exhaustive.
- (b) *Significance.* Explain the potential importance of the proposed work and identify any unique ideas or potential contributions that might result from this study.
- (c) *Relevance to Veterans Health.* Describe the relevance of the proposed work to the VA patient care mission specifically and health issues in general.

(3) **Work Accomplished (6-8 pages recommended).**

- (a) *New applications (including revisions to new applications):* Describe the preliminary/previous studies conducted by the PI that are pertinent to the application. The information should help reviewers evaluate the experience and competence of the investigator to pursue the research. The experience/competence of key collaborators may be briefly described. Up to 5 publications and/or submitted or accepted manuscripts by the PI may be placed in the appendix.
- (b) *Renewal applications:* In addition to describing relevant preliminary studies, a progress report is required for all renewal applications. Provide the beginning and ending dates for the

last period of funding. Summarize the previous program's specific aims/objectives as well as changes to the specific aims due to budget reductions. Discuss the progress made toward achieving the specific aims by providing a succinct account of relevant published and unpublished results of work funded by the previous application. In the section entitled "Publications From Previous Funding Period," provide complete references for all publications, manuscripts submitted or accepted for publication, patents or other printed materials that have resulted from this project during its last funding period. Up to 5 publications and/or submitted or accepted manuscripts may be placed in the appendix.

(4) Work Proposed

- (a) Provide a timetable describing the sequence of the proposed research.
- (b) It is useful to specifically relate each experiment to particular hypotheses/key questions. Describe the research design, methods, and procedures to be used to accomplish the specific aims of the application.
- (c) Describe the experimental design/approach and how the data will be collected, analyzed and interpreted. Describe new methodologies to be used and why they are preferred over existing methods.
- (d) Discuss potential problems and limitations of the proposed methods/procedures and possible alternative procedures to achieve the specific aims.
- (e) If humans or animals are to be studied, power analysis should be used to justify the number to be studied. Justify the species of animal to be used even if it is contained in the Animal Component of Research Proposal (ACORP). If cell lines or tissue specimens are used, discuss the source of the material.
- (f) The Narrative section must be comprehensible without reference to any other document.

k. **Human Studies Section (no limit, be succinct - not included in 25-page limit for narrative).** If form 10-1313-1, Block 19, Human Subjects is checked "Yes," create a section heading titled "Human Subjects." Applicants must address the involvement of human subjects and protections from research risk relating to their participation in the proposed research plan. In this section, provide information to **address all four evaluation criteria below** as they apply to the research proposed. **Applications that fail to comply will be withdrawn without review.**

(1) Risk to Subjects

(a) *Human Subjects Involvement and Characteristics*: Describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as pregnant women, prisoners, institutionalized individuals, or others who may be considered vulnerable populations.

(b) *Sources of Materials*: Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

(c) *Potential Risks*: Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. Differentiate the therapeutic risk from research risk. Therapeutic risk is the risk or potential risks associated with an intervention that is required for medical care but occurs as part of the research. An example is an endoscopy that was required for medical follow-up of a specific illness. Research risk is associated with an intervention that is done for research purposes only regardless if it is an experimental intervention or a commonly used intervention, for example, an extra endoscopy. Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

(2) Adequacy of Protection from Risks

(a) *Recruitment and Informed Consent*: Describe plans for the recruitment of subjects and the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document may not be submitted at this time.

(b) *Protection Against Risk*: Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. In studies that involve interventions, describe the plan for data and safety monitoring of the research to ensure the safety of subjects.

(3) Potential Benefit of the Proposed Research to the Subject and Others. Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

(4) Importance of the Knowledge to be gained. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

1. **Animal Subjects (no page limit, be succinct - not included in 25-page limit for narrative)**. If form 10-1313-1, Block 19, Animal Subjects is checked “Yes,” create a section heading entitled “Animal Subjects.” In this section, provide information to **address all five evaluation criteria below** as they apply to the research proposed. **Applications that fail to comply will be withdrawn without review.**

Failure to address the following elements will result in the application being withdrawn without review.

(1) Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

(2) Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

(3) Provide information on the veterinary care of the animals involved.

(4) Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

(5) Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

m. **Resources (1 page limit – not included in 25-page limit for narrative).**

(1) Describe the facilities to be used to conduct the proposed research. Specifically indicate the performance sites (location with specific room numbers and indicate VA space or off-site).

(2) Describe the equipment, capabilities and capacities, their relative proximity and the extent of availability to the project. Include a description of common resource space and equipment available to the proposed research.

(3) Describe laboratory and equipment used to generate the preliminary data and if the equipment is available to the proposed research.

(4) If clinical space will be used, describe the location, availability and purpose.

(5) Do not describe resources that are available but will not be used for the proposed research.

(6) If a VA investigator (PI or VA co-investigator) will perform any portion of the proposed research in assigned off-site space, a copy of an approved off-site waiver must be included in the application. If any of the proposed work will be done in VA leased space, a copy of the approval for the use of the lease must be included. If a non-VA co-investigator (a person neither paid by nor on a without compensation appointment with the VA) will complete specific portions of the proposed work in their off-site laboratory, no waiver is needed.

n. **Publications from Last Funding Period.** List the complete references of all publications, manuscripts that are accepted or submitted, patents or other printed material from the PI and/or collaborators that are based on work accomplished toward the specific aims/objectives of the previous funding period.

o. **Literature Citations (4-page limit).** Include a complete citation for all references (all authors, year, title, journal, volume number and inclusive pages). Start each citation on a new line. List citations by number in the order they first appear in the application. For renewals, the list may include, but does not replace, the citations in “Publications from Last Funding Period.”

p. **Endorsements (Formal letter are required).**

- Letter are needed from participating or effected organization, for example: other VAMC’s, or University Departments.
- Letters are needed from each individual named as a consultant for collaborator explaining their contributions and commitment to the proposal. If the consultant or collaborator has a VA appointment, make sure the endorsement letter is on VA letterhead.

- All other administrative letters are completed by the Research Office.

q. **Page Numbering.** Type the last name of the PI in the lower right corner of each page and number each page consecutively, starting with the VA Form 10-1313-1 (e.g., Smith-1 to Smith-37).

r. **Page Numbering.** Type the last name of the PI in the lower right corner of each page and number each page consecutively, starting with the VA Form 10-1313-1 (e.g., Smith-1 to Smith-37).

SUBMIT THE FOLLOWING TO THE RESEARCH OFFICE BY FEBRUARY 13

The signed original only and any manuscripts (eight copies) are needed in the Research Office. We make the 25 copies and send them into VA Central Office.

Include the “Research Priority Area-Portfolio,” this form is available on the Iowa City Research website, www.research.iowa-city.med.va.gov.

Include the “Suggested Reviewers,” this form is available on the Iowa City Research website, www.research.iow-city.med.va.gov.